Section 5: 510(k) Summary

K102219

SEP 24 2010

Device Information:

Category	Comments
Sponsor:	Socorro Medical, Inc. 450 Sutter Street, Suite 500 San Francisco, CA 94108 Contact: Ed Diao, M.D. ediao@sf-sc.com 415-362-8880
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Surgical Knife
Device Classification & Code:	Class II (due to specific claims, otherwise Class I), EMF
Device Classification Name:	21 CFR 878.4800
Device Proprietary Name:	Socorro SMI Tunnel Release Device

Predicate Device Information:

Predicate Device:	A.M. Surgical Mountable Endoscopic Blade
Predicate Device Manufacturer:	A.M. Surgical, Inc.
Predicate Device Common Name:	Surgical Knife
Predicate Device Classification:	21 CFR 878.4800
Predicate Device Classification & Code:	Class II, EMF
Premarket Notification Number:	K080133

b. Date Summary Prepared
18 June 2010

c. Description of Device
The SMI Tunnel Release Device is comprised of a hand piece with a tissue cutting probe which is used in conjunction with an endoscope camera and fiber optic illumination system. The device is supplied sterile and is for single use only.

The hand piece provides an actuation member for extending, retracting, and angularly rotating surgical blades which are attached to the distal end of the hand piece. Basic features of these probes are a retraction region and visualization that is nearly three-hundred and sixty degrees (360°).

The visualization scope connects with the camera head and optic cables which provide the surgeon a clear and complete view of the surgical site on the overhead monitor.

The endoscope is used to illuminate and visualize the anatomy in or around the operative site. It allows the physician to directly visualize the actions of the probe during the procedure and to verify complete excision of the targeted tissue.

d. Intended Use

The Socorro SMI Tunnel Release Device is intended for the minimally invasive examination, isolation and recession/incision of ligament, tendons, or fascia as in:

-Plantar Fasciotomy,
-Carpal Tunnel Release,
-Elbow Cubital Tunnel Release and
-Gastrocnemius Tenotomy.

e. Comparison to Predicate Device

The Socorro SMI Tunnel Release Device is substantially equivalent in intended use, technology, design and materials to the A.M. Surgical Mountable Endoscopic Blade (K080133).

The Socorro SMI Tunnel Release Device and its predicate all provide technology to access and relieve an entrapment neuropathy that occurs when a nerve or tendon at the wrist, elbow, knee, ankle or heel is compressed by a thickened tendon sheath, edema or soft-tissue mass. An endoscope is guided into the joint through a small incision(s) above and/or below the affected joint. Small cutting tools (mechanical blades) are then used to excise the tendon sheath or mass under direct observation.

The patient contacting components that make up the application device and its predicate is stainless steel. The blades are provided sterile and are for single use only. Other components of the predicate device are sterilized between uses while the entire application device is provided sterile and is for single use only.

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

Socorro Medical concludes that the devices are substantially equivalent.

f. Summary of Supporting Data

Bench testing has demonstrated that the device is in compliance with international standards, the expectations of the medical community and the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Socorro Medical, Inc.
% Coombs Medical Device Consulting
Mr. Craig Coombs
1193 Sherman Street
Alameda, California 94501

SEP 24 2010

Re: K102219
Trade/Device Name: Socorro SMI Tunnel Release Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, EMF
Dated: September 20, 2010
Received: September 22, 2010

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Steven Runner
Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

K102219

510(k) Number (if known):

SEP 24 2010

Device Name: Socorro SMI Tunnel Release Device

Indications For Use:

The Socorro SMI Tunnel Release Device is intended for the minimally invasive examination, isolation and recession/incision of ligament, tendons, or fascia as in:

-Plantar Fasciotomy,
-Carpal Tunnel Release,
-Elbow Cubital Tunnel Release and
-Gastrocnemius Tenotomy.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Neil R. P. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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